Paper No. 22

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte CHRISTOPHER F. BIGGE,
THOMAS C. MALONE,
and FRANK WATJEN

Appeal No. 1998-2089
Application 08/443,507

ON BRIEF

Before WINTERS, WILLIAM F. SMITH, and GRIMES, Administrative Patent Judges.

WINTERS, Administrative Patent Judge.

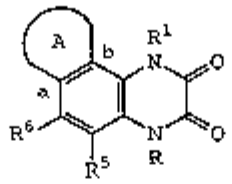
DECISION ON APPEAL

This appeal was taken from the examiner's decision rejecting claims 1, 3 through 7, 9 through 14, 17, 19, and 24, which are all of the claims pending in the application.

REPRESENTATIVE CLAIMS

Claims 1 and 17, which are illustrative of the subject matter on appeal, read as follows:

1. A compound having the formula



or a pharmaceutically acceptable salt thereof wherein

R is hydrogen or hydroxy;

R^1 is hydrogen,

alkyl,

arylalkyl,

$(CH_2)_nOH$, or

$(CH_2)_nNR^7R^8$;

R^5 and R^6 are each independently

hydrogen,

halogen,

NO_2,

CN,

CF_3,

$SO_2NR^7R^8$,

$PO_3R^9R^{10}$,

alkyl,

alkenyl,

alkynyl,

$(CH_2)_nCONR^7R^8$,

$(CH_2)_nCO_2R^{10}$,

$NHCOR^{11}$,

wherein R^7 and R^8 are each independently hydrogen or alkyl,

R^9 is hydrogen or alkyl,

R^{10} is hydrogen or alkyl,

R^{11} is hydrogen or alkyl, and

n is an integer of from zero to four;

A is a ring of six atoms fused with the benzo ring at the positions marked a and b, and formed by the following bivalent radicals:

a-CHR^{14}-CH_2-NR^{12}-CHR^{13}-b,

a-CHR^{13}-NR^{12}-CH_2-CHR^{14}-b,

a-CH_2-CH_2-CHR^{13}-NR^{12}-b,

a-NR^{12}-CHR^{13}-CH_2-CH_2-b,

wherein

R^{12} is hydrogen, CH_2CH_2OH, or alkyl, and R^{13} and R^{14} are each independently hydrogen, CN, $CONH_2$, CH_2NH_2, CH_2OH, alkyl, arylalkyl, alkenyl, or CO_2R^{15}, wherein R^{15} is hydrogen or alkyl.

17. A pharmaceutical composition comprising a therapeutically effective amount of a compound of Claim 1 together with a pharmaceutically acceptable carrier.

THE PRIOR ART

In rejecting applicants' claims, the examiner does not rely on any prior art references.

THE ISSUE

The issue presented for review is whether the examiner erred in rejecting claims 1, 3 through 7, 9 through 14, 17, 19 and 24 under 35 U.S.C. § 112, first paragraph, as based on a non-enabling disclosure.

DELIBERATIONS

Our deliberations in this matter have included evaluation and review of the following materials: (1) the instant specification, including all of the claims on appeal; (2) applicants' Appeal Brief and Reply Brief before the board; (3) the Examiner's Answer (Paper No. 15); and (4) the communication from the examiner mailed February 13, 1998 (Paper No. 19).

On consideration of the record, including the above-listed materials, we affirm the examiner's rejection under 35 U.S.C. § 112, first paragraph.

DISCUSSION

We find no error in the examiner's determination that applicants' specification does not teach those skilled in the art how to use the full scope of the claimed invention without undue experimentation. On reflection, we agree with the position ably and thoroughly presented in the Examiner's Answer including (1) the statement of rejection under 35 U.S.C. § 112, first paragraph, and (2) the response to applicants' arguments

on appeal. We therefore adopt that position as our own, adding the following remarks for emphasis only.

Applicants rely on four references to show the state of prior art at time their invention was made. These references are:

> Sheardown, et al. (Sheardown), "2,3-Dihydroxy-6-nitro-7-sulfamoyl-benzo(F)quinoxalime: A Neuroprotectant for Cerebral Ischemia," Science, Vol. 247, pp. 571-574, 1990
>
> Meldrum, "Excitatory amino acids in epilepsy and potential novel therapies," Epilepsy Research, Vol. 12, pp. 189-196, 1992
>
> Smith, et al. (Smith), "The non-N-methyl-D-aspartate receptor antagonists, GYKI 52466 and NBQX are anticonvulsant in two animal models of reflex epilepsy," Eur. J. of Pharm., Vol. 201, pp. 179-183, 1991
>
> Meldrum, "Excitatory amino acid receptors and disease," Current Opinion in Neurology and Neurosurgery, Vol. 5, pp. 508-513, 1992

Applicants have attached copies of these references to their Appeal Brief, and argue that the state of the prior art weighs in favor of a determination that their disclosure is enabling. We disagree. First, as pointed out by the examiner, only the Sheardown reference is of record. The other references have not been made part of the administrative record, and have not been considered by the examiner (Examiner's Answer, Paper No. 15, page 14; communication mailed by the examiner February 13, 1998, Paper No. 19). Nor shall they be considered by us. Second, in our judgment, the examiner has adequately responded to applicants' argument based on the Sheardown reference (Examiner's Answer, pages 14 and 15).

Applicants rely on a description of four assays in their specification, pages 14 and 15, as establishing that (1) the claimed compounds have utility, and (2) the specification teaches any person skilled in the art how to use the full scope of the

claimed compounds. We disagree. Again, the examiner has adequately responded to applicants' argument based on the "four assays" (Examiner's Answer, pages 8 through 14). We note particularly the "maximal electroshock assay" described in the specification, page 15, lines 3 through 9, which is said to be performed "by conventional methods as described previously (Krall, et al., Epilepsia 1978; 19:409-428)."[1] According to applicants, they need make only one credible assertion of a specific utility for the claimed invention to satisfy 35 U.S.C. § 101 and 35 U.S.C. § 112, first paragraph; and the claimed compounds meet that test because they possess anticonvulsant activity based on the anticonvulsant drug screening protocol described by Krall (Appeal Brief, page 6). The examiner argues, however, that applicants have not followed Krall's standard procedure for performing the maximal electroshock assay (Examiner's Answer, page 13). Additionally, the examiner argues that the drug screening protocol outlined by Krall involves a combination of three tests. Only one of those tests is the maximal electroshock assay. As correctly found by the examiner, "[t]here is no evidence that the rest of the standard screening protocol has been done" (Examiner's Answer, page 14, first paragraph). In conclusion, the examiner argues, and we agree, that applicants performed only one test of the "three-screen protocol" outlined by Krall for anticonvulsant drug screening; and even with respect to that test, the "maximal electroshock assay," applicants did not follow Krall's standard procedure.

We also invite attention to In re Wands, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed Cir 1988), where the court enumerated a number of factors which may be

[1] Applicants include a copy of the Krall reference as an attachment to their Appeal Brief.

considered in determining whether a disclosure would require undue experimentation. These factors are:

> (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.

Here, claim 1 on appeal covers a large area in view of the recitation of variables R, R^1, R^5, R^6, and A. Claim 1 is broad in scope.[2]

Further, as stated in In re Fisher, 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970), "in cases involving unpredictable factors, such as most chemical reactions and physiological activity, the scope of enablement obviously varies inversely with degree of unpredictability of the factors involved." Here, we agree with the examiner that applicants' claimed invention involves a relatively high degree of unpredictability. The claims at issue are drawn to quinoxalinedione derivatives, said to be useful for treating various neurodegenerative disorders by administering same to a mammal (including a human patient) in need of such treatment. The claimed invention involves unpredictable factors such as physiological activity, pharmacology, and therapeutic action of specified quinoxalinedione derivatives.

Also, the very nature of applicants' invention involves therapeutically active ingredients for administration to a mammal, including a human patient, in need of

[2] In their Appeal Brief, page 3, first paragraph, applicants group all of the appealed claims together. Accordingly, for the purposes of this appeal, we have treated claim 3 through 7, 9 through 14, 17, 19, and 24 as standing or falling together with claim 1.

treatment for a variety of neurodegenerative disorders. These disorders include, inter alia, lathyrism, Alzheimer's disease, Huntington's disease, schizophrenia, Parkinson's disease, epilepsy, drug addiction, and a number of cerebrovascular disorders. We agree with the examiner that, at the time applicants' invention was made, it was recognized by persons having ordinary skill in the art that these disorders were difficult to treat, i.e., resistant to effective pharmaceutical treatment.

All in all, we believe that the examiner appropriately assessed the state of the prior art; the four assays described in applicants' specification; the breadth of claim 1; the unpredictability of the art; and the nature of the invention, in determining that applicants' specification does not teach those skilled in the art how to use the full scope of the claimed invention without undue experimentation.

The examiner's decision is affirmed.

No time period for taking any subsequent action in connection with this appeal may be extended under 37 CFR § 1.136(a).

AFFIRMED

Sherman D. Winters Administrative Patent Judge	)
William F. Smith Administrative Patent Judge	) BOARD OF PATENT)) APPEALS AND)) INTERFERENCES
Eric Grimes Administrative Patent Judge	)

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